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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,947	07/31/2003	Alastair Hodges	104978-172	4975

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LIFESCAN/NUTTER MCCLENNEN & FISH LLP
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1753	

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07/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,947	HODGES ET AL.	
	Examiner	Art Unit	
	Kaj K. Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5-7-2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The outstanding objection to the specification is withdrawn in view of the amendment of 5-7-2007.

Claim Objections

2. Claim 5 is objected to because of the following informalities: The inserted "(Original " between the "meta" and "l" is clearly a typo. Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-8, 11, 12, 14-20, 22, 24 and 27-30 of U.S. Patent No. 6,638,415. Although the conflicting claims are not identical, they are not patentably distinct from each other.

5. As discussed in the previous office action, all the previous limitations of claims 1-20 were contained in the limitations of claims 1-3, 6-8, 11, 12, 14-20, and 27-30. Applicant has amended claim 1 to specify that the reagent is disposed on a support. Claim 22 of the patent discloses the presence of a support and claim 24 discloses disposing (i.e. containing) the reagent on the support. Hence, claim 1 of the instant invention still fully encompasses the claims of the patent.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 8-12 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Diebold et al (USP 5,437,999).

8. Diebold discloses a device comprising an electrochemical cell having a sensing chamber 49, a first electrode (17, 20), a second electrode (8, 11), an aperture 50 for admitting the sample in the sensing chamber. See fig. 1, 2, 5, and 6 and col. 5, ll. 3-15, col. 6, ll. 25-34, and col. 8, ll. 15-60. Diebold further discloses a reagent contained within the sample chamber (col. 10, ll. 14-

60). Because the reagent in question is a osmium bypyridine complex, which is also disclosed by the instant invention (claim 9), it is inherently capable of undergoing a redox reaction directly with an analyte (including for oxidizing an antioxidant) to generate an electrical signal. With respect to the quantity of reagent being sufficient for only a single test, this would be met by Diebold regardless of whether Diebold had only enough reagent for one test or enough reagent for multiple tests, because the claims are constructed with open language (i.e. "comprising" and "contains"). Even if Diebold contained more than enough reagent, it would still contain enough reagent for only a single test.

9. Applicant has amended claim 1 to specify that the reagent is disposed on a support where the support is selected from at least a wall of the electrochemical cell, independent support or self support. This limitation does not read free of the teaching of Diebold for a number of reasons. First, Diebold teaches that the reagent is disposed on the electrode surface. See col. 10, ll. 25-29. Because the electrode surface would reasonably constitute a wall of the electrochemical cell (i.e. electrode elements 32 and 46 define the upper and lower bounds of the sensor sample volume and thereby read on the defined "walls"), then Diebold's deposition of the reagent onto one or both electrodes would read on disposing the reagent onto at least one wall of the electrochemical sensor. Second, Diebold teaches that the reagent is combined with a polymer matrix. See col. 11, l. 67 through col. 12, l. 17. A polymer matrix would read on an "independent support" because it is independent substance from the reagent itself. Finally, applicant appears to define "self support" in the specification as being where the reagent supports itself. See paragraph 0044. Hence, even if Diebold didn't support the reagent on any wall of the cell or didn't utilize any additional matrix or membrane element, Diebold would still read on the

defined "self support" because applicant's "self support" appears to be merely defining that the reagent supports itself (i.e. there is no support *per se*). The reagent of Diebold is clearly supporting itself.

10. With respect to the compositions of the first and second electrodes, see claims 15 and 16 of Diebold.

11. With respect to the use of a reagent that can reduce an oxidant, Diebold also teaches the use of a ferrocyanide salt (col. 12, ll. 27-32), which the instant invention evidences is capable of reducing an oxidant.

12. With respect to the use of a buffer, see Table 1 in col. 10.

13. With respect to the presence of an interface for connection to a meter, see col. 8, ll. 33-36. The interface would conduct both voltage and current. See col. 1, ll. 13-25.

14. With respect to the cell being a thin layer electrochemical cell, the device of Diebold would read on the defined "thin" giving the claim language its broadest reasonable interpretation.

15. Claims 7, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold in view of Nankai et al (USP 5,120,420).

16. With respect to claim 7, Diebold set forth all the limitations of the claim, but did not explicitly recite the use of a reference electrode in addition to the first and second electrodes. Nankai teaches in an alternate electrochemical cell that a three-electrode embodiment of a sensor (by adding a reference electrode) is more accurate than a two-electrode embodiment of the sensor. See col. 13, ll. 6-12. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Nankai for the sensor of Diebold so as to provide a more accurate electrochemical sensor.

17. With respect to claim 13, Diebold set forth all the limitations of the claim, but did not explicitly disclose the use of any of the set forth buffer solutions. Nankai also teaches that a phosphate buffer is a conventional choice as a buffer for the reagent layer. See col. 4, l. 62 through col. 5, l. 5. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Nankai for the sensor of Diebold because the substitution of one known buffer for another known buffer requires only routine skill in the art.

18. With respect to claim 17, Diebold set forth all the limitations of the claim, but did not specify the distance between the first and second electrode. Nankai teaches that the spacer width that defines the capillary passage for the sensor should not be too large because that would require larger samples and would impede the capillary wicking of fluid into the chamber. Nankai taught that the spacer should be preferably down to 50 microns and more preferably down to 100 microns. See col. 12, ll. 43-54. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Nankai for the sensor of Diebold such that the sensor requires less sample and facilitates capillary wicking of the fluid. It is noted that Diebold is also interested in minimizing the amount of sample required for analysis. See the abstract and col. 12, ll. 39-42. Because the width of the measuring chamber in Diebold is the same thing as the spacing between the first and second electrodes, the incorporation of the spacing from Nankai for the measuring chamber of Diebold would result in a distance between the two electrodes of less than 150 microns.

19. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diebold in view of Graves et al (USP 5,342,498).

20. Diebold set forth all the limitations of the claims, but did not explicitly teach the use of a heater for heating the sample. Graves teaches in an alternate electrochemical sensor that the addition of a heating element allows the temperature of the sensor and analyte to be precisely controlled (see abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Graves for the sensor of Diebold in order to provide a narrower sensor temperature range, which allows for more accurate measurements.

Response to Arguments

21. Applicant's arguments filed 5-7-2007 have been fully considered but they are not persuasive. Applicant urges that Diebold does not read on the new limitations of claim 1 because Diebold teaches that the reagent is applied to the working electrode. However, as discussed in the revised rejection above, the electrodes of Diebold would read on a wall of the electrochemical cell. Nowhere in claim 1 does it exclude electrodes from reading on the defined walls of the claims. Moreover as discussed above, the examiner also urged that the use of a polymer matrix of Diebold would read on the defined support as well. Finally, the examiner also urged that applicant's defined "self support" appears to read on the use of no support *per se* at all (i.e. this limitation covers when the reagent is its own support). Hence, applicant's use of the choice of "self support" appears to read on the use of no support at all.

22. Applicant's traversal of the rejections relying on Nankai or Graves appear to rely on the perceived failings of Diebold against the preceding claims. Because the examiner is not in

agreement about these perceived failings, the rejections relying on Nankai and Graves are also being maintained.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
July 19, 2007

KAJ K. OLSEN
PRIMARY EXAMINER